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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,950	07/19/2001	Robert C. Getts	4081.006	1927

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EXAMINER
HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental

Office Action Summary	Application No. 09/908,950	Applicant(s) GETTS ET AL.	
	Examiner Shar Hashemi	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-38 are indefinite because in claims 1 & 19 it is unclear whether "corresponding feature" refers to the capture reagent or the microarray probe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 7-8, 10, 12-13, 15, 17-22, 25-26, 28-29, 31 & 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skouv (US 6,303,315 B1 October 16, 2001) in view of Chee et al (US 6, 355, 431 March 12, 2002).

Claims 1-4, 7-8, 10, 12-13, 15, 17-22, 25-26, 28-29, 31 & 34-38 are drawn to a method for determining a specific nucleotide sequence in an RNA reagent, comprise incubating a mixture of two components in order to allow the capture sequence to hybridize to the complementary nucleotide sequence and form a pre-hybridized RNA-capture reagent complex, the first component having an RNA reagent with a target nucleotide sequence and a capture sequence, the second component having a capture reagent that is made of a first arm containing a label capable of emitting a detectable signal and a second arm containing a nucleotide sequence complementary to the capture sequence from the first component, contacting the complex with a microarray containing a probe nucleotide sequence, incubating the complex by allowing the hybridization of the target nucleotide sequence and the probe nucleotide sequence, emitting a detectable signal after the target nucleotide sequence hybridizes to the probe nucleotide sequence, and generating a detectable hybridization pattern for subsequent analysis. Claim 2 which is drawn to claim 1 with the further limitation of a dendrimer. Claim 18 which is drawn to claim 1 with the further limitation of blocking nucleic acids. Claim 37 which is drawn to claim 1 with the further limitation of locked nucleic acids.

Skouv in US 6,303,315 B1 teaches a method for ribonucleic acid detection (see whole document especially col. 10, lines 36-64). They teach extracting RNA from a target sample (col. 11, lines 19-25). They teach a RNA reagent consisting of a target nucleotide sequence and a capture sequence (col.7, lines 1-7). They teach a capture reagent having a first arm that is capable of emitting a detectable signal and a second arm having a nucleotide sequence complementary to the capture sequence (col. 7, lines 1-10). They teach the first incubating step, comprise hybridizing the capture sequence to the complementary nucleotide sequence to form a

pre-hybridized RNA-capture reagent complex (col.25, lines 23-35). They teach contacting the complex with a probe nucleotide sequence (col. 25, lines 44-55). They teach the second incubating step, comprise hybridizing the target nucleotide sequence to the complementary probe nucleotide sequence (col. 26, 1-15). They teach hybridization resulting in the emission of the detectable signal (col. 26, lines 31-43). They teach the capture reagent is nucleic acid (col. 7, lines 1-3). They teach passing a base to purge the hybridized RNA reagent from the probe nucleotide sequence (col. 25, lines 36-38). They teach the RNA reagent and capture reagent are incubated for 30 minutes (col. 25, line 67). They teach the complex is incubated for 30 minutes (col. 26, line 4). They teach the probe nucleotide sequences comprises cDNA (col. 7, lines 42-54). They teach the probe nucleotide sequences comprise oligonucleotides (col. 17, lines 60-65). They teach washing the free unhybridized complex (col. 9, lines 15-29). They teach adding blocking nucleic acids after the first incubation step (col. 19, lines 54-60). They teach a capture sequence having a locked nucleic acid nucleotide (col. 17, lines 15-24).

Skouv in US 6,303,315 B1 do not teach microarray. They do not teach dendrimers. They do not teach a single-stranded RNA oligonucleotide having an adenine base. They do not teach a single-stranded oligonucleotide having a thymine base.

Chee et al (US 6, 355, 431) teach microarray utilizing a probe nucleotide sequence (page 44, paragraph 2). They teach dendrimers (page 40, paragraph 6). They teach a single-stranded RNA oligonucleotide having adenine and thymine bases (page 17, paragraph 2). They teach the probe nucleotide sequences comprise cDNA (page 17, paragraph 2).

One of ordinary skill at the time the invention was made would have been motivated to apply Chee et al's (US 6, 355, 431) microarray technique to Skouv's (US 6,303,315 B1) method

for ribonucleic acid detection in order to perform simultaneous analysis on numerous samples (page 43, paragraph 8). It would have been prima facie obvious to apply Chee et al's (US 6, 355, 431) microarray technique to Skouv's (US 6,303,315 B1) method for ribonucleic acid detection in order to perform simultaneous analysis on numerous samples in a rapid, inexpensive manner (page 44, paragraph 3).

3. Claims 6 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skouv (US 6,303,315 B1 October 16, 2001) in view of Chee et al (US 6, 355, 431 March 12, 2002) and in further view of Shimizu et al (US 5,391,653 February 21, 1995).

The teachings and suggestions of Skouv and Chee are described previously.

Skouv in US 6,303,315 B1 does not teach a 0.05 M sodium hydroxide base solution.

Shimizu et al in US 5,391,653 teach a 0.05 M sodium hydroxide base solution (col. 14, table 3).

One of ordinary skill at the time the invention was made would have been motivated to apply Shimizu et al's (US 5,391,653) 0.05 M sodium hydroxide base solution to Skouv's and Chee's method for ribonucleic acid detection in order to create an alkaline solution (col.2, lines 65-66) to separate the hybridized RNA from the probe nucleotide sequence. It would have been prima facie obvious to apply Shimizu's 0.05 M sodium hydroxide base solution to Skouv's and Chee's combined method for ribonucleic acid detection in order to create an alkaline solution to separate the hybridized RNA from the probe nucleotide sequence.

4. Claims 5, 9, 11, 14, 16, 23, 27, 30 & 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skouv (US 6,303,315 B1 October 16, 2001) in view of Chee et al (US 6, 355, 431 March 12, 2002) and in further view of Shimizu et al (US 5,391,653 February 21, 1995).

The teachings and suggestions of Skouv and Chee are described previously.

Skouv in US 6,303,315 B1 does not teach a temperature of 55 degrees Celsius during the incubation and separation steps.

English et al in (US 6077824 A June 20, 2000) teach a temperature of 55 degrees Celsius during the incubation and separation steps (col. 87, lines 5-45).

One of ordinary skill at the time the invention was made would have been motivated to apply English et al's (US 6077824 A) temperature of 55 degrees Celsius during the incubation and separation steps to Skouv's and Chee's combined method for ribonucleic acid detection in order to create relatively stringent conditions to form the hybrids (col. 87, lines 5-40). It would have been prima facie obvious to apply English's temperature of 55 degrees Celsius during the incubation and separation steps to Skouv's and Chee's combined method for ribonucleic acid detection in order to form hybrids utilizing relatively stringent conditions.

SUMMARY

5. No claims are allowed.

CONCLUSION

6. Any inquiry concerning this communication or earlier communication should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is Shar.Hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

June 19, 2002

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
7/17/02